REMARKS

Claims 13-22 were cancelled. Claims 1-12 remain in the application. Applicant asserts that no new matter has been added. Reconsideration of the Application is hereby requested

Claim Rejections

Rejections Under 35 U.S.C. § 112

Claims 1 and 10 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

The Office Action asserts that the term "dry … is a relative term which renders the claim indefinite." The Office Action also asserted that the term "substantially dry … is a relative term which renders the claim indefinite."

Initially, regarding use of "substantially," Applicant directs the examiner to MPEP 2173.05(b)(D), which makes clear that use of "substantially" does not render a claim indefinite.

Also, Applicant respectfully traverses the assertion that use of "dry" renders these claims indefinite. "Dry compaction" is a term that has long been well known to those of skill in the art of pharmaceutical manufacturing and has been given construction in patent claims (*see, e.g.,* U.S. Patent No. 5,480,650, issued to Marchi et al. – specifically Claim 2).

In support of its traversal, Applicant submits Exhibits 1 and 2, appended hereto. Exhibit 1, is an excerpt from Pharmaceutics: The Science of Dosage Form Design, 2d Ed., Aulton, Michael E., 2001 – Churchill Livingstone Dimensions, which is the definitive treatise on the art of pharmaceutical dosage manufacturing processes. This excerpt is taken from Chapter 25, entitled "Granulation" and includes a section on "dry granulators" (*see*, p. 378). In this section, the text indicates that "[d]ry granulation converts primary powder particles into granules using the application of pressure without the intermediate use of a liquid."

Exhibit 2 is a copy of an article from a major pharmaceutical industry trade journal,

entitled "The Granulation Process 101: Basic Technologies for Tablet Making" Tousey, Michael D., 2002, Pharmaceutical Technology, pp. 8-13. This article includes a detailed discussion of dry granulation, which states that "[t]he dry granulation process is used to form granules without using a liquid solution…" (p. 12)

Both a major treatise on pharmaceutical manufacturing and a major pharmaceutical trade magazine use the term "dry granulation" consistently with each other. Thus, this term is not indefinite and would be well understood by anyone of skill in the art of pharmaceutical manufacturing and, therefore, the term is definite.

Claim 4 was also rejected under 35 U.S.C. § 112, second paragraph as being indefinite for the same reason discussed in reference to Claims 1 and 10. Applicant asserts that the user of "dry compaction" in Claim 4 is definite for the same reasons discussed above.

Therefore, Applicant believes that this rejection has been overcome a respectfully requests that it be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1-2 and 4-11 were rejected under 35 U.S.C. § 102(b), as being anticipated by Kushla et al. (U.S. Patent No. 6,348,216).

Applicant respectfully asserts that even though the Examiner has rejected the claims under §112 by asserting that "dry" was indefinite, it is improper to write the "dry" limitation out of the claims to sustain a rejection under other sections of the patent code. Dry granulation and compaction are recited in the independent claims and a §102 rejection can be sustained only if a reference discloses *dry* granulation and compaction.

Kushla discloses a composition of ibuprofen and a narcotic analgesic in a single phase (Kushla, col. 3, ll. 12-15). However, Kushla completely fails to disclose any of the following limitations recited in the independent claims: "mixing, in a dry powder phase"; "compacting the ibuprofen, the narcotic analgesic and the at least one excipient to form a substantially dry compact material"; and "milling the dry compact material."

Actually, Kushla *teaches away* from the claimed invention. Specifically, Kushla discloses "[g]ranulating ibuprofen, a narcotic analgesic … to form granules wherein said granulating step comprises *a wet granulation process*" (col. 3, ll. 36-39) (emphasis added). Anyone of skill in the art would recognize that "a wet granulation process" is completely opposite from a dry granulation process.

Because Kushla fails to disclose a *dry* granulation and compaction process, Applicant believes that this rejection has been overcome and respectfully requests that it be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 3 and 12 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Kushla in view of Arnold (U.S. Patent No. 4,587,252).

Kushla completely fails to disclose any sort of *dry* granulation process, as recited in the independent claims. Similarly, Arnold completely fails to disclose any sort of *dry* granulation process. For this reason, the combination of these two references completely fails to teach or suggest the invention recited in the remaining claims.

For these reasons, it is believed that this rejection has been overcome and Applicant respectfully requests that all remaining claims be allowed.

Prior Art Made of Record

In addition to the remarks presented above, Applicant asserts that the remaining prior art made of record neither anticipates, nor renders obvious the claimed invention.

CONCLUSION

Applicant believes that the rejections have been overcome for the reasons recited above. Therefore, Applicant respectfully requests that all remaining claims be allowed and that a timely Notice of Allowance be issued.

No addition fees are believed due. However, the Commissioner is hereby authorized to charge any additional fees that may be required, including any necessary extensions of time, which are hereby requested, to Deposit Account No. 503535.

05/21/2007
Date

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